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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/007,483

12/05/2001

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03/25/2005

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,483	Applicant(s) GORYSHIN ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/7/02 and 3/22/0</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-18 are pending.

Receipt of the Information Disclosure statements of 11/7/02 and 3/22/02 is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8 in the reply filed on 12/6/04 is acknowledged. The traversal is on the ground(s) that a search of any of the other groups set forth in the restriction requirement would reveal art relevant to the subject matter of Group I, that the polynucleotides set forth in the claims of Group I are utilized in methods of the other groups, and that a search of the subject matter of all groups would not be unduly burdensome. This is not found persuasive because as was previously set forth in the requirement for election mailed 9/22/04, the polynucleotide of Group I could be utilized in methods other than those set forth in the methods of the instant claims, and the method claims comprise different method steps and results. It is noted that each element of the claims must be searched, and arguments that the Groups share a common concept or theme does not account for this. Similarly, common or overlapping classification does not recognize the fact that the search in the biotechnology area requires a search of non-patent literature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/6/04.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the drawings that lack sequence identifiers (see Fig. 1). It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 1 and 5-8 are drawn to a polynucleotide comprising distinct first and second transposase-interacting inverted repeat sequence pairs, each pair having a specificity for binding to and interacting with a distinct transposase enzyme. Claim 3 is dependent on claim 1, reciting that the first or second transposase interacting inverted repeat sequence pair comprises Tn5 mosaic end sequences. The specification has not provided a definition of the term "Tn5 mosaic end sequences", although it provides an example, at page 8 of the specification. Claims 1 and 5-8 are genus claims in terms of polynucleotides comprising any distinct first and second transposase-interacting inverted repeat sequence pairs, each pair having a specificity for binding to and interacting with a distinct transposase enzyme. Claim 3 is a genus claim for the a polynucleotide comprising first or second transposase interacting inverted repeat sequence pairs which comprises any Tn5 mosaic end sequences. The claims encompass a broad class of polynucleotides comprising inverted sequence pairs of any sequence, or any "Tn5 mosaic end sequences", which are specific for binding to an interacting with any distinct

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transposase enzyme. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed polynucleotides based on the teachings of the specification. While the specification provides general information on regions of the Tn5 polynucleotide and the use of its inside and outside ends in the claimed polynucleotide, there is no disclosure of a structure-function analysis of the Tn5 sequences to provide guidance on the essential regions of the polynucleotides that could be modified and retain function. There is no guidance regarding the structure of sequences other than those present in the Tn5 transposase which would interact with distinct transposase enzymes. Therefore, the specification does not describe the claimed polynucleotides in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the products claimed at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Vas-Cath V. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides comprising first and second transposase-interacting inverted repeat sequence pairs, each sequence pair having a specificity for binding to and

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interacting with a distinct transposase enzyme, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only polynucleotides comprising Tn5 wild-type inside end sequences, outside end sequences, or the Tn5 mosaic sequence disclosed in the specification, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite in the recitation of "Tn5 mosaic end sequences". The specification does not give a definition of this term, stating only that "[t]he so-called mosaic end sequences ("ME") of US Patent No. 5,925,545 can be advantageously used in the present invention instead of wild-type OE sequences. Where "ME" sequences are used in the patent application, it is understood that ME and wild type OE sequences can be used, although use of ME yields a higher transposition frequency" (page 8, lines 2-5). Therefore, it is not clear what is intended by this phrase, and the intended subject matter cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Reznikoff (Ann Rev. Microbiol., 47:945-963, 1993) in view of Reznikoff et al. (US Patent 6,406,896)(cited for evidence purposes only) and Reznikoff 5,965,443 (cited on 1449 form filed 3/22/02) (cited for evidence purposes only).

Reznikoff disclose a polynucleotide comprising distinct first and second transposase-interacting inverted repeat sequence pairs, each sequence pair having a specificity for binding to and interacting with a distinct transposase enzyme, members of the first sequence pair flanking members of the second sequence pair (see Tn5, Fig. 1). The first transposase-interacting inverted repeat sequence pair comprises Tn5 wild-type outside end sequences, the second transposase-interacting inverted repeat sequence pair comprises Tn5 wild-type inside end sequences. The polynucleotide comprises a first sequence for conferring selectability upon a host cell (kan^r) between the members of the second inverted repeat sequence. Reznikoff et al. '896 (cited for evidence purposes only) teach that Tn5 inside end sequence pairs are specifically bound by a mutant altered transposase (see column 2, lines 31-50). Reznikoff et al. '443 teach that Tn5 outside end sequence pairs are specifically bound by a distinct mutant altered transposase (see claims, see also statement in the instant disclosure, page 7, paragraph 34). Therefore, the two pairs of transposase-interacting inverted repeat sequence pairs of Tn5 have specificity for binding to and interacting with two distinct transposase enzymes, and the first pair flanks the second pair.

Conclusion

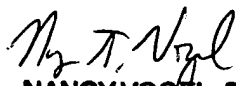
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NANCY VOGEL, PH.D.
PATENT EXAMINER